ADOPTED

Senator Carter of the 1st offered the following amendment:

Amend the House substitute to SB 418 (SB 418/HCSFA) by striking lines 1 through 531 and inserting in lieu thereof the following:

To amend Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled substances, so as to provide for the establishment of a program for the monitoring of prescribing and dispensing Schedule II, III, IV, or V controlled substances; to provide for definitions; to require dispensers to submit certain information regarding the dispensing of such controlled substances; to provide for the confidentiality of submitted information except under certain circumstances; to provide for the establishment of an Electronic Database Review Advisory Committee; to provide for its membership, duties, and organization; to provide for the establishment of rules and regulations; to provide for limited liability; to provide for penalties; to provide for related matters; to provide for an effective date; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Chapter 13 of Title 16 of the Official Code of Georgia Annotated, relating to controlled substances, is amended by revising Code Section 16-13-21, relating to definitions relative to regulation of controlled substances, as follows:

"16-13-21.

As used in this article, the term:

(0.5) 'Addiction' means a primary, chronic, neurobiologic disease with genetic, psychosocial, and environmental factors influencing its development and manifestations. It is characterized by behaviors that include the following: impaired control drug use, craving, compulsive use, and continued use despite harm. Physical dependence and tolerance are normal physiological consequences of extended opioid therapy for pain and are not the same as addiction.

(1) 'Administer' means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or by any other means, to the body of a patient or research subject by:

(A) A practitioner or, in his or her presence, by his or her authorized agent; or

(B) The patient or research subject at the direction and in the presence of the practitioner.

(2) 'Agent' of a manufacturer, distributor, or dispenser means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

(2.1) 'Board' means the State Board of Pharmacy.

(3) 'Bureau' means the ~~Drug Enforcement Administration, United States Department of Justice, or its successor agency~~ Georgia Bureau of Investigation.

(4) 'Controlled substance' means a drug, substance, or immediate precursor in Schedules I through V of Code Sections 16-13-25 through 16-13-29 and Schedules I through V of 21 C.F.R. Part 1308.

(5) 'Conveyance' means any object, including aircraft, vehicle, or vessel, but not including a person, which may be used to carry or transport a substance or object.

(6) 'Counterfeit substance' means:

(A) A controlled substance which, or the container or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, number, or device, or any likeness thereof, of a manufacturer, distributor, or dispenser other than the person who in fact manufactured, distributed, or dispensed the controlled substance;

(B) A controlled substance or noncontrolled substance, which is held out to be a controlled substance or marijuana, whether in a container or not which does not bear a label which accurately or truthfully identifies the substance contained therein; or

(C) Any substance, whether in a container or not, which bears a label falsely identifying the contents as a controlled substance.

(6.1) 'Dangerous drug' means any drug, other than a controlled substance, which cannot be dispensed except upon the issuance of a prescription drug order by a practitioner authorized under this chapter.

(6.2) 'DEA' means the United States Drug Enforcement Administration.

(7) 'Deliver' or 'delivery' means the actual, constructive, or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship.

(8) 'Dependent,' 'dependency,' 'physical dependency,' 'psychological dependency,' or 'psychic dependency' means and includes the state of ~~dependence by an individual toward or upon a substance, arising from the use of that substance, being characterized by behavioral and other responses which include the loss of self-control with respect to that substance, or a strong compulsion to use that substance on a continuous basis in order to experience some psychic effect resulting from the use of that substance by that individual, or to avoid any discomfort occurring when the individual does not use that substance~~

adaptation that is manifested by drug class specific signs and symptoms that can be produced by abrupt cessation, rapid dose reduction, decreasing blood level of the drug, and administration of an antagonist. Physical dependence, by itself, does not equate with addiction.

(9) 'Dispense' means to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery, or the delivery of a controlled substance by a practitioner, acting in the normal course of his or her professional practice and in accordance with this article, or to a relative or representative of the person for whom the controlled substance is prescribed.

(10) 'Dispenser' means ~~a practitioner who dispenses~~ a person that delivers a Schedule II or III controlled substance to the ultimate user but shall not include:

(A) A licensed pharmacy of a hospital that dispenses such substances for the purpose of inpatient or outpatient hospital care, a licensed pharmacy of a hospital or retail pharmacy of a hospital that dispenses prescriptions for controlled substances at the time of dismissal or discharge from such a facility, or a licensed pharmacy of a hospital or retail pharmacy of a hospital that dispenses or administers such substances for long-term care patients or inpatient hospice facilities;

(B) An institutional pharmacy that serves only a health care facility, including, but not limited to, a nursing home, an intermediate care home, a personal care home, or a hospice program, which provides inpatient care and which pharmacy dispenses such substances to be administered and used by a patient on the premises of the facility;

(C) A practitioner or other authorized person who administers such a substance; or

(D) A pharmacy operated by, on behalf of, or under contract with the Department of Corrections for the sole and exclusive purpose of providing services in a secure environment to prisoners within a penal institution, penitentiary, prison, detention center, or other secure correctional institution. This shall include correctional institutions operated by private entities in this state which house inmates under the Department of Corrections.

(11) 'Distribute' means to deliver a controlled substance, other than by administering or dispensing it.

(12) 'Distributor' means a person who distributes.

(12.05) 'FDA' means the United States Food and Drug Administration.

(12.1) 'Imitation controlled substance' means:

(A) A product specifically designed or manufactured to resemble the physical appearance of a controlled substance~~,~~ such that a reasonable person of ordinary

knowledge would not be able to distinguish the imitation from the controlled substance by outward appearances; or

(B) A product, not a controlled substance, which, by representations made and by dosage unit appearance, including color, shape, size, or markings, would lead a reasonable person to believe that, if ingested, the product would have a stimulant or depressant effect similar to or the same as that of one or more of the controlled substances included in Schedules I through V of Code Sections 16-13-25 through 16-13-29.

(13) 'Immediate precursor' means a substance which the State Board of Pharmacy has found to be and by rule identifies as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

(14) 'Isomers' means stereoisomers (optical isomers), geometrical isomers, and structural isomers (chain and positional isomers;) but shall not include functional isomers).

(15) 'Manufacture' means the production, preparation, propagation, compounding, conversion, or processing of a controlled substance, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation, compounding, packaging, or labeling of a controlled substance:

(A) By a practitioner as an incident to his or her administering or dispensing of a controlled substance in the course of his or her professional practice; or

(B) By a practitioner or by his or her authorized agent under his or her supervision for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale.

(16) 'Marijuana' means all parts of the plant of the genus Cannabis, whether growing or not, the seeds thereof, the resin extracted from any part of such plant, and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or resin; but shall not include samples as described in subparagraph (P) of paragraph (3) of Code Section 16-13-25 and shall not include the completely defoliated mature stalks of such plant, fiber produced from such stalks, oil, or cake, or the completely sterilized samples of seeds of the plant which are incapable of germination.

(17) 'Narcotic drug' means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:

(A) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate;

(B) Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical ~~with~~ to any of the substances referred to in subparagraph (A) of this paragraph, but not including the isoquinoline alkaloids of opium;

(C) Opium poppy and poppy straw;

(D) Coca leaves and any salt, compound, derivative, stereoisomers of cocaine, or preparation of coca leaves, and any salt, compound, stereoisomers of cocaine, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions of coca leaves which do not contain cocaine or ecgonine.

(18) 'Opiate' means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Code Section 16-13-22, the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

(19) 'Opium poppy' means the plant of the species Papaver somniferum L., except its seeds.

(19.1) 'Patient' means the person who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed.

(20) 'Person' means an individual, corporation, government, or governmental subdivision or agency, business trust, estate, trust, partnership, or association, or any other legal entity.

(21) 'Poppy straw' means all parts, except the seeds, of the opium poppy after mowing.

(22) 'Potential for abuse' means and includes a substantial potential for a substance to be used by an individual to the extent of creating hazards to the health of the user or the safety of the public, or the substantial potential of a substance to cause an individual using that substance to become dependent upon that substance.

(23) 'Practitioner' means:

(A) A physician, dentist, pharmacist, podiatrist, ~~veterinarian,~~ scientific investigator, or other person licensed, registered, or otherwise authorized under the laws of this state to distribute, dispense, conduct research with respect to, or to administer a controlled substance in the course of professional practice or research in this state;

(B) A pharmacy, hospital, or other institution licensed, registered, or otherwise authorized by law to distribute, dispense, conduct research with respect to, or to

administer a controlled substance in the course of professional practice or research in this state;

(C) An advanced practice registered nurse acting pursuant to the authority of Code Section 43-34-25. For purposes of this chapter and Code Section 43-34-25, an advanced practice registered nurse is authorized to register with the federal Drug Enforcement Administration and appropriate state authorities; or

(D) A physician assistant acting pursuant to the authority of subsection (e.1) of Code Section 43-34-103. For purposes of this chapter and subsection (e.1) of Code Section 43-34-103, a physician assistant is authorized to register with the federal Drug Enforcement Administration and appropriate state authorities.

(23.1) 'Prescriber' means a physician, dentist, scientific investigator, or other person licensed, registered, or otherwise authorized under the laws of this state to prescribe, distribute, dispense, conduct research with respect to, or administer a controlled substance in the course of professional practice or research in this state.

(24) 'Production' includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance.

(25) 'Registered' or 'register' means registration as required by this article.

(26) 'Registrant' means a person who is registered under this article.

(26.1) 'Schedule II or III controlled substance' means a controlled substance that is classified as a Schedule II or III controlled substance under Code Section 16-13-26 or 16-13-27, respectively, or under the Federal Controlled Substances Act, 21 U.S.C. Section 812.

(27) 'State,' when applied to a part of the United States, includes any state, district, commonwealth, territory, insular possession thereof, or any area subject to the legal authority of the United States.

(27.1) 'Tolerance' means a physiologic state resulting from regular use of a drug in which an increased dosage is needed to produce a specific effect or a reduced effect is observed with a constant dose over time. Tolerance may or may not be evident during opioid treatment and does not equate with addiction.

(28) 'Ultimate user' means a person who lawfully possesses a controlled substance for his or her own use, for the use of a member of his or her household, or for administering to an animal owned by him or her or by a member of his or her household or an agent or representative of the person.

(29) 'Noncontrolled substance' means any drug or other substance other than a controlled substance as defined by paragraph (4) of this Code section."

SECTION 2.

Said chapter is further amended by adding new Code sections to read as follows:

"16-13-57.

(a) Subject to funds as may be appropriated by the General Assembly or otherwise available for such purpose, the board shall, in consultation with members of the Georgia Composite Medical Board, establish and maintain a method to electronically record into a data base prescription information which results in the dispensing of Schedule II or III controlled substances and to electronically review such prescription information that has been entered into such data base. The purpose of such electronic data base and review process shall be to assist in the reduction of the abuse of controlled substances, to improve, enhance, and encourage a better quality of health care by promoting the proper use of medications to treat pain and terminal illness, and to reduce duplicative prescribing and overprescribing of controlled substance practices.

(b) Such electronic data base and review process shall be administered by the board at the direction and oversight of the board.

16-13-58.

(a) The board shall apply for available grants and may accept any gifts, grants, donations, and other funds, including funds from the disposition of forfeited property, to assist in developing and maintaining the electronic data base established pursuant to Code Section 16-13-57.

(b) The board shall be authorized to grant funds to dispensers for the purpose of covering costs for dedicated equipment and software for dispensers to use in complying with the reporting requirements of Code Section 16-13-59. Such grants shall be funded by gifts, grants, donations, or other funds, including funds from the disposition of forfeited property, received by the board for the operation of the electronic data base established pursuant to Code Section 16-13-57. The board shall be authorized to establish standards and specifications for any equipment and software purchased pursuant to a grant received by a dispenser pursuant to this Code section. Nothing in Code Sections 16-13-57 through 16-13-64 shall be construed to require a dispenser to incur costs to purchase equipment and software to comply with such Code sections.

(c) Nothing in Code Sections 16-13-57 through 16-13-64 shall be construed to require any appropriation of state funds.

16-13-59.

(a) For purposes of the electronic data base and review process established pursuant to Code Section 16-13-57, each dispenser shall submit to the board by electronic means

information regarding each prescription dispensed for a Schedule II or III controlled substance. The information submitted for each prescription shall include at a minimum, but shall not be limited to:

(1) United States Drug Enforcement Administration (DEA) permit number or approved dispenser facility controlled substance identification number;

(2) Date prescription dispensed;

(3) Prescription serial number;

(4) If the prescription is new or a refill;

(5) National Drug Code (NDC) for drug dispensed;

(6) Quantity and strength dispensed;

(7) Number of days supply of the drug;

(8) Patient's name;

(9) Patient's address;

(10) Patient's date of birth;

(11) Approved prescriber identification number or prescriber's DEA permit number;

(12) Date prescription issued by prescriber; and

(13) Other data elements consistent with standards established by the American Society for Automation in Pharmacy, if designated by regulations of the board.

(b) Each dispenser shall submit the prescription information in accordance with transmission methods and frequency requirements established by the board on a weekly basis and shall report, at a minimum, prescriptions dispensed up to 72 hours prior to data submission. If a dispenser is temporarily unable to comply with this subsection due to an equipment failure or other circumstances, such dispenser shall notify the board.

(c) The board may issue a waiver to a dispenser that is unable to submit prescription information by electronic means acceptable to the board. Such waiver may permit the dispenser to submit prescription information to the board by paper form or other means, provided all information required in subsection (a) of this Code section is submitted in this alternative format subject to the frequency requirements of subsection (b) of this Code section. Requests for waivers shall be submitted in writing to the board.

(d) The board shall not revise the information required to be submitted by dispensers pursuant to subsection (a) of this Code section more frequently than annually. Any such change to the required information shall neither be effective nor be applicable to dispensers until six months after the adoption of such changes.

(e) The board shall not access electronic data base prescription information for more than two years after the date it was originally received, and after two years, all such information shall be deleted or destroyed in a timely and secure manner.

(f) A hospital, clinic, or other health care facility may apply to the board for an exemption to be excluded from compliance with this Code section if compliance would impose an undue hardship on such facility. The board shall provide guidelines and criteria for what constitutes an undue hardship which shall include criteria relating to the number of indigent patients served and the lack of electronic capabilities of the facility.

16-13-60.

(a) Prescription information submitted to the board pursuant to Code Section 16-13-59 shall be confidential and shall not be subject to open records requirements, as contained in Article 4 of Chapter 18 of Title 50, except as provided in subsections (c) and (d) of this Code section.

(b) The board shall establish and maintain strict procedures to ensure that the privacy and confidentiality of patients and prescribers and patient and prescriber information collected, recorded, transmitted, and maintained pursuant to Code Sections 16-13-57 through 16-13-64 are protected. Such information shall not be disclosed to persons except as otherwise provided in Code Sections 16-13-57 through 16-13-64 and only in a manner which in no way would conflict with the requirements of the federal Health Insurance Portability and Accountability Act (HIPAA) of 1996, P.L. 104-191.

(c) The board shall be authorized to provide requested prescription information collected pursuant to Code Sections 16-13-57 through 16-13-64:

(1) To persons authorized to prescribe or dispense controlled substances for the purpose of providing medical or pharmaceutical care for their patients;

(2) Upon the request of a person about whom the prescription information requested concerns or upon the request on his or her behalf by his or her attorney;

(3) To the Georgia Composite Medical Board or any licensing board whose practitioners have the authority to prescribe or dispense controlled substances;

(4) Upon receipt of a subpoena issued by a court of record, located within or outside of this state, to any local, state, or federal law enforcement, regulatory, or prosecutorial officials;

(5) Upon the lawful order of a court of competent jurisdiction; and

(6) To personnel of the board for purposes of administration and enforcement of Code Sections 16-13-57 through 16-13-64 or any other applicable state law.

(d) The board may provide data to government entities for statistical, research, educational, or grant application purposes after removing information that could be used to identify prescribers or individual patients or persons who received prescriptions from dispensers.

(e) The board may prepare a plan to provide electronic data base prescription information to a prescription review program in another state if the confidentiality, security, privacy, and utilization standards of the requesting state are determined to be equivalent to those of the board.

(f) Any person who receives electronic data base prescription information or related reports relating to Code Sections 16-13-57 through 16-13-64 from the board shall not provide such data or reports to any other person except by order of a court of competent jurisdiction or as otherwise permitted pursuant to Code Sections 16-13-57 through 16-13-64.

(g) Any permissible user identified in Code Sections 16-13-57 through 16-13-64 who directly accesses electronic base prescription information shall implement and maintain a comprehensive information security program that contains administrative, technical, and physical safeguards that are appropriate to the user's size and complexity and to the sensitivity of the personal information obtained. The permissible user shall identify reasonably foreseeable internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, or other compromise of the information and shall assess the sufficiency of any safeguards in place to control the risks.

16-13-61.

(a) There is established an Electronic Database Review Advisory Committee for the purposes of consulting with and advising the board on matters related to the establishment, maintenance, and operation of how prescriptions are electronically reviewed pursuant to Code Sections 16-13-57 through 16-13-64. This shall include, but shall not be limited to, data collection, regulation of access to data, evaluation of data to identify benefits and outcomes of the reviews, communication to prescribers and dispensers as to the intent of the reviews and how to use the data base, and security of data collected.

(b) The advisory committee shall consist of eight members as follows:

(1) A representative from the board;

(2) A representative from the Georgia Composite Medical Board;

(3) A representative from the Georgia Board of Dentistry;

(4) A consumer representative, appointed by the board;

(5) A representative from a specialty profession that deals in addictive medicine, appointed by the board;

(6) An oncologist, appointed by the board;

(7) A representative from a hospice or hospice organization, appointed by the board; and

(8) A representative from the State Board of Optometry.

(c) Each member of the advisory committee shall serve a three-year term or until the appointment and qualification of such member's successor.

(d) The advisory committee shall elect a chairperson and vice chairperson from among its membership to serve a term of one year. The vice chairperson shall serve as the chairperson at times when the chairperson is absent.

(e) The advisory committee shall meet at the call of the chairperson or upon request by at least three of the members and shall meet at least one time per year. Five members of the committee shall constitute a quorum.

(f) The members shall receive no compensation or reimbursement of expenses from the state for their services as members of the advisory committee.

16-13-62.

The board shall establish rules and regulations to implement the requirements of Code Sections 16-13-57 through 16-13-64. Nothing in Code Sections 16-13-57 through 16-13-64 shall be construed to authorize the board to establish policies, rules, or regulations which limit, revise, or expand or purport to limit, revise, or expand any prescription or dispensing authority of any prescriber or dispenser subject to Code Sections 16-13-57 through 16-13-64.

16-13-63.

Nothing in Code Sections 16-13-57 through 16-13-64 shall require a dispenser or prescriber to obtain information about a patient from the prescription monitoring program established pursuant to Code Sections 16-13-57 through 16-13-64. A dispenser or prescriber shall not have a duty and shall not be held liable for damages to any person in any civil, criminal, or administrative action for injury, death, or loss to person or property on the basis that the dispenser or prescriber did or did not seek or obtain information from the electronic prescriptions data base established pursuant to Code Section 16-13-57.

16-13-64.

(a) A dispenser who knowingly and intentionally fails to submit electronic data base prescription information to the board as required by Code Sections 16-13-57 through 16-13-64 or knowingly and intentionally submits incorrect prescription information shall be guilty of a misdemeanor and, upon conviction thereof, shall be punished for each such offense by imprisonment for a period not to exceed 12 months, a fine not to exceed $1,000.00, or both, and such actions shall be reported to the board responsible for issuing such dispenser's dispensing license for action to be taken against such dispenser's license.

(b)(1) An individual authorized to access electronic data base prescription information pursuant to Code Sections 16-13-57 through 16-13-64 who negligently uses, releases, or discloses such information in a manner or for a purpose in violation of Code Sections 16-13-57 through 16-13-64 shall be guilty of a misdemeanor. Any person who is convicted of negligently using, releasing, or disclosing such information in violation of Code Sections 16-13-57 through 16-13-64 shall, upon the second or subsequent conviction, be guilty of a felony and shall be punished by imprisonment for not less than one nor more than three years, by a fine not to exceed $5,000.00, or by both.

(2) An individual authorized to access electronic data base prescription information pursuant to Code Sections 16-13-57 through 16-13-64 who knowingly and intentionally uses, releases, or discloses such information in a manner or for a purpose in violation of Code Sections 16-13-57 through 16-13-64 shall be guilty of a felony and, upon conviction thereof, shall be punished by imprisonment for not less than two nor more than ten years, by a fine not to exceed $100,000.00, or by both. Any person who is convicted of knowingly and intentionally using, releasing, or disclosing such information in violation of Code Sections 16-13-57 through 16-13-64 shall, upon the second or subsequent conviction, be guilty of a felony and shall be punished by imprisonment for not less than three nor more than 15 years, by a fine not to exceed $250,000.00, or by both.

(c) Any person who knowingly requests, obtains, or attempts to obtain electronic data base prescription information pursuant to Code Sections 16-13-57 through 16-13-64 under false pretenses, or who knowingly communicates or attempts to communicate electronic data base prescription information to any board, agency, or person except in accordance with Code Sections 16-13-57 through 16-13-64, or any member, officer, employee, or agent of the board or the advisory council, or any person who knowingly falsifies electronic data base prescription information or any records relating thereto shall be guilty of a felony and, upon conviction thereof, shall be punished for each such offense by imprisonment for not less than one year nor more than two years, by a fine not to exceed $5,000.00, or by both.

(d) Any person who is injured by reason of any violation of Code Sections 16-13-57 through 16-13-64 shall have a cause of action for the actual damages sustained and, where appropriate, punitive damages. Such person may also recover attorney's fees in the trial and appellate courts and the costs of investigation and litigation reasonably incurred.

(e) The penalties provided by this Code section are intended to be cumulative of other penalties which may be applicable and are not intended to repeal such other penalties."

SECTION 3.

This Act shall become effective on July 1, 2010.

SECTION 4.